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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,301	12/19/2001	Maurice R. De Billot	17396/09015	8087
27530	7590	02/22/2006	EXAMINER	
NELSON MULLINS RILEY & SCARBOROUGH, LLP			CLARDY, S	
1320 MAIN STREET, 17TH FLOOR			ART UNIT	
COLUMBIA, SC 29201			PAPER NUMBER	

1617

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,301	Applicant(s) DE BILLOT ET AL.	
	Examiner S. Mark Clardy	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 103-106, 108-118, 120-122 and 134-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 103-105, 108-111, 113-115, 117, 118, 120, 121 and 134-158 is/are rejected.
- 7) ☒ Claim(s) 106, 112, 116, 122 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 103-106, 108-118, 120-122, and 134-158, are pending in this application.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 106, 112, 116, and 122 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. These claims are drawn to the methods of using the fungicide silthiofam, and are clearly enabled by the disclosure. Further, no reference or combination of references suggests the ability of silthiofam to increase vigor and/or yield of transgenic soybean plants.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 103-105, 108-111, 113-115, 117, 118, 120, 121, and 134-158 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d

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1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

All claims are drawn to the elected invention (Groups II and III), i.e., the method of increasing the vigor and/or the yield of a plant by treatment with: 1) a fungicide that is ineffective against fungal pathogens for the treated plant, in combination with 2) a herbicide for which the plant has been genetically modified to be resistant. The elected species comprises treating glyphosate-ready soybean (*Glycine max*) with:

- a. silthiofam (fungicidal component)
- b. glyphosate (herbicidal component)
- c. *Rhizobium* spp. (inoculating fungi).

(2) The state of the prior art

The active agents encompassed by the claims are known fungicidal agents. However, the state of the art would not extend to applying fungicidal compounds when they are selected *because* they are ineffective for a given plant's known fungal pathogens. Fungicidal agents are

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not expected to increase the vigor and/or yield of the agronomic plants to which they are applied, except by virtue of their ability to kill fungal pathogens.

(3) The relative skill of those in the art

The relative skill of those in the art is high. One skilled in the art would recognize, or be able to readily determine, the spectrum of activity for a known fungicide and whether it is applicable for the fungal pathogens which are known to infect a given plant species. By extension, it would be straightforward to determine which fungicides are *not* effective, and thus fall within the scope of the instant claims for a given plant species.

(4) The predictability or unpredictability of the art

The unpredictability of the fungicidal art is very high, particularly in using fungicides for a non-fungicidal utility. It is unpredictable whether any given fungicidal compound will possess the ability to increase the vigor and/or yield of the agronomic plants to which they are applied. Once a fungicidal agent within the scope of the claims is selected, there is no method other than experimentation to determine whether it does, in fact, possess the ability to increase the vigor and/or yield of the agronomic plants to which they are applied.

(5) The breadth of the claims

The claims are very broad, encompassing all known fungicidal agents, for application to any genetically modified herbicide resistant plant.

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(6) The amount of direction or guidance presented

The guidance presented in the specification and claims is sufficient to select a fungicide, herbicide, and target agronomic plant that will fall within the scope of the claims. However, the guidance is not sufficient to enable one of ordinary skill in the art to be reasonably certain that any given combination selected in accordance with the claims will actually work.

(7) The presence or absence of working examples

The disclosure provides working examples for carrying out the claimed method of applying the fungicide silthiofam to CSR2121 soybean plants in order to increase vigor and/or yield (see “1”, above). No other fungicides, herbicides, or agronomic plants have been tested.

(8) The quantity of experimentation necessary

Every proposed combination of fungicide and herbicide will have to be tested to determine whether the combination does, in fact, possess the ability to increase the vigor and/or yield of the transgenic agronomic plants to which it is applied. There is no reasonable expectation of success inasmuch as the fungicidal component is intentionally selected to preclude its known utility as a fungicide. There is no teaching or suggestion in the art that fungicides in general are capable of enhancing yield and vigor of plants just by virtue of being in the class of “fungicides”. This class of active agents is quite extensive both structurally and metabolically, thus it is unreasonable to extrapolate a broad activity such as plant growth enhancement to the entire class of fungicides. There is no more reason to expect any fungicide selected in

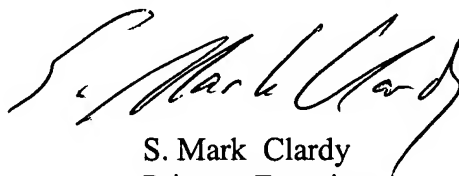
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accordance with the invention to increase vigor and/or yield, than there is to expect it to do absolutely nothing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Mark Clardy whose telephone number is 571-272-0611. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Mark Clardy', with a stylized flourish at the end.

S. Mark Clardy
Primary Examiner
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February 15, 2006